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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,026	03/26/2004	David N. Edwards	068660.0127	9801

31625 7590 08/22/2006

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EXAMINER	
JOIKE, MICHELE K	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/811,026	EDWARDS, DAVID N.	
	Examiner	Art Unit	
	Michele K. Joike, Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

The abstract of the disclosure is objected to because it is unclear from the specification how the cDNA population can be inserted into the hybrid proteins, as stated in lines 7 and 8. Correction is required. See MPEP § 608.01(b).

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Figure 1 contains nucleotide sequences that need a sequence identifier.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4-10, and 12-16 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,103,472 (102(e) date: 2/20/1998, hereinafter Thukral).

Applicant teaches a method of producing hybrid proteins from a hybrid gene cDNA library comprising a vector containing a selectable marker and a sequence encoding a hybrid protein comprising a regulatable DNA sequence, a MCS 3' to the regulatable sequence and a DNA sequence encoding a common peptide 3' to the MCS. The multiple cloning site does not contain a translational termination sequence; the common peptide does not contain a translational initiation codon. The method further comprises isolating mRNA and synthesizing a cDNA population using random primers and inserting the cDNA into the MCS. The vector is transformed into bacterial cells and yeast cells where the protein is expressed. The bacterial cells are *E. coli*. The hybrid protein region in the vector contains a transcription termination sequence at the 3' end of the common peptide.

Thukral teaches a method of constructing a cDNA library and inserting the library into a signal trap vector to generate a signal trap library (hybrid gene library of instant claim 1, see col. 2, lines 40-50). The signal trap library (hybrid gene library) taught by Thukral is constructed with vectors such that DNA sequences which control expression of selection or marker genes, cDNA inserts, and reporter genes are operably linked to said cDNA and genes and that the signal sequences are inserted in frame to the reporter polypeptide coding sequences (see col. 7, lines 5-15). Thukral teaches that the vector is pYYa-41L which is an *E. coli* –yeast shuttle vector that contains a Bla1 gene for ampicillin resistance and TRP1 gene for propagation in yeast (see col. 7, lines 15-19). With regard to instant claim 1, Thukral also teaches that the vector contains in order 5' to 3' an ADH promoter (regulatable DNA sequence), a polylinker containing

unique Xhl and Not I sites to facilitate directional cloning of random primed cDNAs (multiple cloning site that does not encode a translational termination sequence and placed immediately 3' to the regulatable DNA sequence, see also col. 10, lines 34-37), a leaderless a-amylase gene encoding amino acids 29-624 of a-amylase (a DNA sequence encoding at least one common peptide and not containing a translation initiation codon which is placed 3' to the multiple cloning site) (see col. 7, lines 20-26), or amino acids 82-624 (see col. 10, lines 58-67). See also example 3 for construction of hybrid gene cDNA library. Although Thukral does not explicitly state that the multiple cloning site does not contain a translational termination sequence, such is an inherent teaching of Thukral because the hybrid protein that is constructed, as taught by Thukral, contains the protein encoded by the random primed cDNA on the N-terminal side fused to the leaderless a-amylase protein (common peptide) on the C-terminal side. Thukral teaches that after the a-amylase sequence, the vector contains an ADH terminator sequence (see col. 7, lines 23 and 24).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thukral in view of Moynihan et al and in further view of US 5,310,663 (hereinafter Dobeli).

Claims 3, 11 and 17 add the limitation that the common peptide comprises six successive histidine residues and the hybrid protein is purified using affinity purification.

Thukral et al teaches all of the limitations as described above. However, Thukral et al do not teach a common peptide sequence comprising six successive histidine residues and purifying the protein using affinity purification.

Moynihan et al (J Biol. Chem. 274(43): 30963-30968, 1999, specifically Materials & Methods) teaches a yeast two-hybrid screen comprising a vector containing ampicillin as the selectable marker and a sequence encoding a hybrid protein comprising a the ADH1 promoter, a MCS 3' to the promoter and a DNA sequence encoding a GAL4 AD (common peptide) 3' to the MCS. Although Moynihan et al do not explicitly state that the multiple cloning site does not contain a translational termination sequence, such is an inherent teaching because the hybrid protein that is constructed contains the protein encoded by the cDNA on the N-terminal side fused to the leaderless GAL4 AD (common peptide) on the C-terminal side. The method further comprises isolating mRNA and synthesizing a cDNA population and inserting the cDNA into the MCS. The vector is transformed into both *E. coli* and yeast. The protein is affinity purified from yeast as a GST fusion protein. However, Moynihan et al does not teach use of a His tag for affinity purification.

Dobeli et al (specifically columns 1 and 6) teach the use of a 6X His tag for affinity purification.

The ordinary skilled artisan, desiring to produce hybrid proteins from a hybrid gene cDNA library with the method described above, would have been motivated to combine the teachings of Thukral teaching a method of constructing a cDNA library and inserting the library into a signal trap vector to generate a signal trap library, with Moynihan et al teaching a yeast two-hybrid screen and affinity purifying a GST fusion protein with Dobeli teaching the use of a 6X His tag for affinity purification, because Dobeli states that it would be advantageous to purify the desired recombinant proteins in the form of fusion proteins in one step using the affinity peptide. It would have been obvious to one of ordinary skill in the art to use a 6X His tag because the His tag can be linked directly or indirectly to the biologically active protein. Given the teachings of the prior art and the level of the ordinary skilled artisan at the time of the applicant's invention, it must be considered, absent evidence to the contrary, that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Allowable Subject Matter

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike, Ph.D. whose telephone number is 571-272-5915. The examiner can normally be reached on M-F, 9:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele K Joike, Ph.D.
Examiner
Art Unit 1636

DAVID GUZO
PRIMARY EXAMINER